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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/618,235 | 07/18/2000 | Donn Nelton Rubingh | 7670 | 8554 |

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THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
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EXAMINER

MOORE, WILLIAM W

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1652

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/618,235

Applicant(s)

RUBINGH ET AL.

Examiner

William W. Moore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8/2003.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Interview Summary and Response to Amendment

In an Appeals Conference in Technical Center 1600 of the USPTO on October 16, 2003, that considered Applicant's Brief on Appeal filed August 6, 2003, it was decided that the rejections of record of claims 1-6, 8, 9 and 20 herein under 35 U.S.C. § 103(a) over Von der Osten et al. in view of Braxton and claim 21 over Von der Osten et al. and Braxton in view of Powell et al., all of record, should be withdrawn because insufficient motivation existed to make the epitope-masking modification taught by Braxton at any site identified by Von der Osten et al. Claim amendments that conform pending claims to the modified protease species elected for examination herein were requested of Applicant in a telephonic interview on October 17, 2003, and Applicant duly presented such an amendment on October 20, 2003, which has been entered. A review, however, of the claim recitations require that new grounds of rejection be stated under the second paragraph of 35 U.S.C. § 112 thus this communication is not made final.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite in failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention where it sets forth a trivalent "addition moiety" showing an "X" having a bond that extends to no particular molecule – yet ~~presumably extends, see claim 3, to a protease moiety which is one of the six elected~~ subtilisin BPN'-correspondent positions identified in claim 1 as the protease that bears a conjugate – and two further bonds that extend to separate molecules "R₁" and "R₂", explaining in a following clause that "X" may either be a "linking moiety" or "nil", and that

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either or both of the further, separate, molecules "R₁" and "R₂" may be one of a first, or second, polypeptide, a first, or a second, polymer, or "nil", so long as one of "X", "R₁", and "R₂" is present, as recited in the phrase "not nil". This description, which must be included in the descriptions of claims 1 and 19-21, also subject to this rejection, where claim 2 depends from claim 1, and is also included in descriptions of claims 3-18 which depend from claim 2, is ambiguous and inaccurate because "nil" means "nothing" according to Webster's Ninth New Collegiate Dictionary (Merriam-Webster 1990) and the final claim term, "not nil", must be taken as a double negative, "not nothing". In addition, a "linking moiety" that is "X" that is "nil" contradicts the subject matter of claim 1 since the result cannot be a conjugate, independently rendering claims 2-18 indefinite.

Claims 1-21 are further indefinite because claims 2-19, which have limitations which must be incorporated in claims 1, 20 and 21, all attempt to make a distinction between, see claim 2, a "first polymer" and a "first polypeptide", or between a "second polymer" and a "second polypeptide" where no such distinction is possible. This is because a polypeptide is a polymer of amino acids. Neither the specification nor the claims make a distinction between heteropolymers and homopolymers, thus an amendment to claims 2, 14, 15, and 19 that substitutes the term "non-peptide polymer" for "polymer" would address this aspect of the rejection. Claim 9 is independently indefinite because, no matter what "X" might be, a "protease conjugate" of claims 6 and 1 from which claim 9 depends cannot have anything conjugated to the protease of claim 1.

While recitations of "nil" may be appropriate in the forum in which the instant application and claims were drafted, recitations of "nil" are indefinite in descriptions of chemical moieties of claims 2, 8, 9, and 13-15 in this national forum. Applicant intends to describe the absence of a component of a "linking moiety" in claims 3-12 and 14-18 and in claim 13 intends that the intermediate component, "X", in a "linking moiety" be no more than a covalent bond. Thus an amendment to claims 2, 8, and 13-15 that

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describes the **presence or absence** of either of the separate molecules "R₁" and "R₂" in a linking moiety and defines "X" either as a linking "molecule", see pages 12-14 of the specification, or as a covalent bond, thus avoiding the issue of its absence, will address this aspect of the rejection. Claim 8 may recite, e.g., "[a] protease conjugate according to Claim 6 wherein R₂ is absent." Unless Applicant intends to describe an intermediate compound not yet conjugated to non-peptide polymer or a polypeptide, in which case an independent claim would be appropriate, resolution of the subject matter of claim 9 does not appear possible.

Claim 6 is independently indefinite because the chain of dependency linking it to claim 1 recites no limitation that distinguishes its subject matter from that of claim 1. Claims 11 is independently indefinite because claim 11 fails to definitely describe the first polypeptide as a further protease distinct from the original protease of the conjugate claims 1 and 6, thus may be construed to describe an intramolecular conjugate, a result not discussed in the specification, thus not clearly intended by the claim. Claim 12 is independently indefinite because it fails to describe how the positions recited are to be identified among the six native proteases and four altered proteases of claim 11. Amending claim 12 to include the recitation in clauses (a)-(c) of claim 1, "'selected from the group of positions corresponding to positions consisting of . . . of the amino acid sequence of subtilisin BPN' set forth in SEQ ID NO:1" will overcome this aspect of the rejection should claim 11 be amended to describe the first polypeptide of claim 8, R₁, as a further protease.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583 until about January 21, 2004, and will be 571.272.0933 thereafter. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at 703.308.3804 until about January 21, 2004, and at 571.272.0928 thereafter. The fax phone numbers for all communications for the organization where this application or proceeding is assigned is 703.872.9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

William W. Moore
December 23, 2003



NASHAAT T. NASHED PHD.
PRIMARY EXAMINER